**State of Georgia (rcvd 2/26/01) :**

In All Agreement States Letter STP 01-007 NRC requested comments on options in the draft proposed rulemaking plan to revise 10 CFR Part 40. In particular, NRC was interested in whether Options 4 and 5 are sufficiently distinct to warrant separation, or whether they should be combined.

Staff reviewed the prm in STP-01-007, and have concluded that Option 4 and Option 5 are distinct enough to choose between them and we think that option 5 is the better of the two. Because of the lack of over sight of general licensees versus specific licensees option 4 would not provide for the required over sight. Since general licensees are not inspected or monitored on as frequent a basis, this option is not a real change from the status quo.

Thomas E. Hill, Manager
Radioactive Materials Program
Georgia Dept of Natural Resources
4244 International Parkway, Suite 114
Atlanta, Georgia 30354
(404) 362-2675

**State of Washington (rcvd 2/27/01):**

We have reviewed the draft Part 40 information found on the Technical Conference Forum and have just posted comments at that site. However, given the short time frame left in the comment period we are forwarding our comments to all Agreement States for your information and opportunity to comment as well.

Regulatory Issue -- The use of 100 millirem per year as the general license "limit" is referenced here as well as in Options 4 and 5. Given that public exposures from these devices or materials could easily come from several different items, shouldn't the same argument prevail as that used for site decommissioning and a limit of 25 mrem per year be used thereby assuring that no one receives more than 100 mrem?

Option 1 -- No comment

Option 2 -- The list of "disadvantages" includes "Increased costs associated with requiring ... licensees ... to become more knowledgeable ..." This should be counterbalanced in the list of "Advantages" with "Likely increased worker awareness of potential hazards due to licensee efforts to become more knowledgeable of Part 20 requirements".

Option 3 -- Gathering information on "distributors" includes those distributing to general licensees. This requires Agreement State efforts to implement and enforce rules on reporting the distributions. Since Agreement States generally have three years to implement NRC regulations, the information from Agreement States likely will not be available. This will create a significant gap in the data gathered by NRC if it goes ahead with a review after two years as stated. If knowledge of actual distribution and uses of source material is as deficient as inferred, how can meaningful regulations, even preliminary ones, be established under Options 4 and 5? It would appear Option 3 (data gathering) is a very important point and should be handled nationwide for best results. However, we suggest a contractor be used to do the research in a short time frame followed by an assessment of the risks involved (six months of sampling rather than 2 years of a regulatory power play to get distributors to cough up all their customers!) Then changes in the regulations would be in order based on the data you infer we now lack.

Option 4 -- The 'tiered" approach is more in line with "risk informed" regulation. We agree that Option 4 should be the recommended approach. However, some effort at data collection needs to be done prior to rule development. We do not believe a 100% knowledge of every distribution is required to assess the risk of such distributions so long as essentially all avenues are identified.

Option 5 -- Delete. This is a "regulatory ratcheting" approach in that a lower limit is immediately set for specific licenses followed by data collection and possible (probable?) further changes. The lower limit for section 40.22 is the only distinction between this Option 5 and Option 4. It is an insufficient difference to be separated out as an Option 5 and should be removed from consideration.

In both Options 4 and 5, a concern is expressed in the "Disadvantages" that a "Legitimate use of material may be discouraged because of increased costs". While this may be a real concern if SAFETY is compromised, the parenthetical example "users may substitute materials or methods that do not use source materials" is improper. It should not be our concern if an economic

decision results in elimination of a route of radiation exposure to the public or workers. After all, that is what ALARA is all about!

Recommended Approach -- We agree that Option 4 should be the preferred Option. Option 5 should be eliminated from consideration. Data gathering and assessment should be emphasized as a preliminary to formulating draft rules and should be accomplished in a "shorter" time frame than the 2 years stated for Option 3 (the new "second choice").

Agreement State Implementation Issues -- We agree that this rule should be Category B (except for distribution of materials to exempt persons) because of the direct transboundary implications.

Enhanced Public Participation -- Unless some effort is made to "get the word out" (beyond posting on the website), the affected "public" and potential licensees, will not be aware of the new rules in a timely manner and thus have no opportunity for input. This is a surefire method to increase the disdain the public has for bureaucratic regulators We recommend that a concerted effort be made to reach distributors and recipients of source material. This could include state and regional press releases, announcements in industry and trade journals, and notification to known distributors requesting the information be forwarded to customers.

Summary of Planned Provisions -- While we agree that the steps listed are reasonable, the "data gathering and assessment" of Option 3 (or 4 or 5) needs to be done prior to "locking these in".

Submitted by John Erickson, Division Director; Gary Robertson, Supervisor, Waste Management; Terry Frazee, Supervisor, Radioactive Materials

**State of Colorado (rcvd 3/2/01):**

March 2, 2001

Gary C. Comfort
Division of industrial and Medical nuclear Safety, NMSS
U. S. Nuclear Regulatory Commission
Washington, DC 20555

RE: PART 40 DRAFT PROPOSED RULEMAKING PLAN (STP-01-007)

The State of Colorado recommend the Commission adopt Option 5 with one modification - that the exemptions from Parts 19 and 20 be completely eliminated.

There were two fundamental principles that behind the OAS-Colorado petition - all persons should be protected equally, and radiation control programs should be able ensure no one is overexposed. Options that merely "minimize" the inconsistencies between the current Part 40 and Part 20 are not acceptable. Experience has shown that source material general licensees can have radiation areas, and can contaminate facilities to levels that exceed release limits. When a facility is identified that exposes individual in excess of Part 20 limits, the regulatory agency must be able to take enforcement action. This can not be done when the regulations exempt the facility.

Colorado agrees a study is needed to improve knowledge of the uses of source material. However, we should provide protections as we gain that knowledge. While evaluation of current practices and distribution practices can determine the level at which to continue a general license, it is unlikely that it will consider all possible uses that could occur, or scenarios where the source material could accumulate, or be used in such a manner as to create a health risk.

If a health risk exists, the NRC should not be prevented from requiring corrective actions. General licensees can create air borne hazards, create radiation areas, and contaminate facilities such that they can not be released for unrestricted use. It would be wrong if this were allowed to continue just because the NRC's evaluation could not foresee all potential uses of source material. Users of generally licensed source materials, and the public around those facilities, deserve the same protection as those using and near general licensees using byproduct material.

We believe Option 5 is superior to Option 4 because the tiered option may be difficult to administer.

Converting existing general licenses into specific licenses need not be overly burdensome on licensees. The proper level of regulatory control can be determined as part of the NRC's Phase II study. Under a specific license, the appropriate level of control by general licensees can be be tailored to the level of risk and addressed in guidance. As information is gained, the guidance can be modified, and eventually codified into regulation as appropriate.

When evaluating the increased burden on source material general licensees, one should not just compare it to the existing burden on them, but also compare them to the requirements for byproduct general licensees.

While Option 2 does address the petitions, and would provide the legal basis to address safety issues, it does nothing to identify which facilities have increased risks due to safety issues.

Option 3, as presented is also unacceptable. Health and safety issues resulting from the use of generally licensed source material have been identified, but Option 3 does not provide a regulatory basis to address these issues. Under Option 3, individual using source material will not receive the same protection as those using byproduct material for approximately an additional 2 years. The reason Colorado petitioned the NRC was to provide the protection of Parts 19 and 20 to all persons.

Including safety notices with the distribution of source material is helpful, but experience has shown that the information is too easily ignored. We do not see requiring general licensees to become more knowledgeable as a disadvantage. Providing information gives those at risk the knowledge to make decisions. Those with a very small risk should also be informed; if they are not, Radiation Control Programs will be contacted to provide the missing information, and the NRC does not include in its regulatory analyses the burden to Radiation Control Programs that result from a lack of knowledge on the part of licensees.

Further, the information gathered under Option 3 does not appear to provide sufficient information to make decisions on the potential risk resulting from the use of source material. Determining how the material is used, as a solid, liquid or vaporized, will identify the potential risk better than the report of sales. Reviews have shown that the same commercial operation can pose significantly different risks depending on their respective radiation safety programs.

A concern with Option 4 is that a multi-tiered general license scheme can quickly become cumbersome, with routine disputes as to what uses should be in what tier. A second problem is that it still provides an exemption requirements necessary to protect health and safety. Even if the exemption were allowed only for very small quantities, a new use or procedure could cause that small quantity to become a concern. Source material users, like those using byproduct material, should be subject to basic radiation safety standards. As long as the exemption exists, there exists a potential for overexposures for which the regulatory agency can not take an action.

Like other options, Option 4 assumes future decisions can be made by gathering data on the distribution of source material. Decisions need to be made based on data about the final use.

We do not see the total elimination of the exemption for generally licensed source material licensees as an undue burden. For example, if the licensee does not expose individuals to ten percent of allowable limits, they will not be required to provide personnel monitoring. Why would individual exposed to byproduct material deserve more protection than those exposed to source material that receive the same dose?

We agree that the rule should be Category B because of the transboundary implications.

W. Jacobi
Program Manager